

## § 1.741

## 37 CFR Ch. I (7–1–09 Edition)

during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities;

(12) A statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including how the length of extension was determined;

(13) A statement that applicant acknowledges a duty to disclose to the Director of the United States Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought (*see* § 1.765);

(14) The prescribed fee for receiving and acting upon the application for extension (*see* § 1.20(j)); and

(15) The name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed.

(b) The application under this section must be accompanied by two additional copies of such application (for a total of three copies).

(c) If an application for extension of patent term is informal under this section, the Office will so notify the applicant. The applicant has two months from the mail date of the notice, or such time as is set in the notice, within which to correct the informality. Unless the notice indicates otherwise, this time period may be extended under the provisions of § 1.136.

[54 FR 9394, Mar. 24, 1987, as amended at 54 FR 30380, July 20, 1989; 56 FR 65155, Dec. 13, 1991; 65 FR 54679, Sept. 8, 2000; 68 FR 14337, Mar. 25, 2003]

### § 1.741 Complete application given a filing date; petition procedure.

(a) The filing date of an application for extension of a patent term is the date on which a complete application is received in the Office or filed pursuant to the procedures set forth in § 1.8 or § 1.10. A complete application must include:

(1) An identification of the approved product;

(2) An identification of each Federal statute under which regulatory review occurred;

(3) An identification of the patent for which an extension is being sought;

(4) An identification of each claim of the patent which claims the approved product or a method of using or manufacturing the approved product;

(5) Sufficient information to enable the Director to determine under subsections (a) and (b) of 35 U.S.C. 156 the eligibility of a patent for extension, and the rights that will be derived from the extension, and information to enable the Director and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the length of the regulatory review period; and

(6) A brief description of the activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities.

(b) If an application for extension of patent term is incomplete under this section, the Office will so notify the applicant. If applicant requests review of a notice that an application is incomplete, or review of the filing date accorded an application under this section, applicant must file a petition pursuant to this paragraph accompanied by the fee set forth in § 1.17(f) within two months of the mail date of the notice that the application is incomplete, or the notice according the filing date complained of. Unless the notice indicates otherwise, this time period may be extended under the provisions of § 1.136.

[52 FR 9394, Mar. 24, 1987, as amended at 59 FR 54503, Oct. 22, 1993; 61 FR 64028, Dec. 3, 1996; 65 FR 54680, Sept. 8, 2000; 69 FR 56546, Sept. 21, 2004]

### § 1.750 Determination of eligibility for extension of patent term.

A determination as to whether a patent is eligible for extension may be made by the Director solely on the basis of the representations contained in the application for extension filed in compliance with § 1.740 or § 1.790. This determination may be delegated to appropriate Patent and Trademark Office